RECEIVED
CENTRAL FAX CENTER

AUG 19 2009

Docket No. CV 0244

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
MICHAEL J. WARING, ET AL.
APPLICATION NO: **09/341,821**
FILED: **SEPTEMBER 1, 1999**
FOR: **MULTI-DOSE WOUND GEL**

Art Unit: **1611**
Examiner: **I. GHALI**

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate of Transmission under 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office
on August 19, 2009
Date

Donna L. Amon
Signature

DONNA L. AMON
Typed or printed name of person signing Certificate

Registration Number, if applicable

908-904 2428
Telephone Number

APPEAL BRIEF

Sir:

(1) REAL PARTY IN INTEREST

The real party in interest in this appeal is ConvaTec Technologies Inc., a Nevada corporation, having a place of business at 6100 Neil Road, Reno, Nevada. ConvaTec

Technologies Inc. is the assignee in the above-identified application by virtue of an assignment which was recorded in the United States Patent and Trademark Office on October 29, 2008 at Reel/Frame 021754/0611; and Linklaters LLP has a security interest by virtue of a security agreement which was recorded in the United States Patent and Trademark office on December 1, 2008, at Reel/Frame 021901/0419.

(2) RELATED APPEALS AND INTERFERENCES

This application was previously appealed. A copy of the decision in Appeal No. 2006-2797 is attached as Appendix (10). The undersigned knows of no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) STATUS OF CLAIMS

Claims 5, 6, 8-10, 14, 15 and 18-20 remain pending in this application. Claims 1-4, 7, 11-13, 16 and 17 were canceled.

Claims 5, 6, 8-10, 14, 15 and 18-20 stand rejected under 35 USC §103 (a).

No claims are allowed.

Claims Appendix (8), annexed hereto, contains a copy of the claims involved in the appeal. The appealed claims are claims 5, 6, 8-10, 14, 15 and 18-20.

(4) STATUS OF AMENDMENTS FILED SUBSEQUENT TO THE FINAL REJECTION

Appellants appeal the decision dated February 19, 2009, of the Primary Examiner, finally rejecting claims 5, 6, 8-10, 14, 15 and 18-20. No amendment to the claims was filed after the final rejection. The Advisory Action mailed July 7, 2009, indicates that the request for reconsideration filed June 19, 2009, was considered but failed to place the application in condition for allowance. Accordingly, claims 5, 6, 8-10, 14, 15 and 18-20 remain pending in this application and stand rejected as set forth in the final Office Action.

(5) SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention relates to and claims a self-sealing barrier aerosol vessel containing multiple doses of a wound gel (see, *e.g.*, page 1, lines 7-10), a method of making a self-sealing barrier aerosol vessel comprising multiple doses of a wound gel (see, *e.g.*, page 3, line 34 - page 4, line 11), methods of treating wounds with a wound gel from a self-sealing barrier aerosol vessel containing multiple doses of a wound gel (see, *e.g.*, page 1, lines 7-10) and a method for dispensing multiple doses of a wound gel from a single dispenser (see, *e.g.*, figure 2).

(6) GROUNDS OF REJECTION TO BE REVIEWED

The sole issue on appeal is whether claims 5, 6, 8-10, 14, 15 and 18-20 were properly rejected under 35 USC §103(a) as being unpatentable over the combined teachings of EP0666081 ('081), U.S. Patent No. 3,788,521 ('521) and U.S. Patent No. 3,976,233 ('233).

(7) ARGUMENTS

(i) Claims 5, 6, 8-10, 14, 15 and 18-20 are patentable under 35 USC §103(a) over the combined teachings of EP0666081 ('081), U.S. Patent No. 3,788,521 ('521) and U.S. Patent No. 3,976,233 ('233).

The rejection of the appealed claims appears to indicate a misunderstanding of the invention. The present invention relates to and claims a self-sealing barrier aerosol vessel containing multiple doses of a wound gel, a method of making a self-sealing barrier aerosol vessel comprising multiple doses of a wound gel, methods of treating wounds with a wound gel from a self-sealing barrier aerosol vessel containing multiple doses of a wound gel and a method for dispensing multiple doses of a wound gel from a

single dispenser. The combined teachings of '081, '521 and '233 do not teach or make obvious the claimed invention.

While '081 does disclose a gel, '081 does not disclose a method of, and a vessel for, safely and efficiently dispensing multiple doses of wound-treating gel where the gel is in gel form in the container, and the vessel's self-sealing characteristic minimizes the contamination of the gel after the use of the vessel.

'223 is cited allegedly to show an aerosol container containing a gel. However, the purpose of the package of '223 is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. According to '223, only the lower chamber of the outer container is pressurized with a gas through a self-sealing plug in the container bottom. See, *e.g.*, column 2, lines 53-57. Since only the lower chamber of the outer container of '223 is pressurized with a gas through a self-sealing plug, the container in '223 is not self-sealing as required in the rejected claims. Moreover, it is submitted that '223 does not address the avoidance of contamination during use. Rather, any avoidance of contamination appears to be with respect to storage. See, *e.g.*, column 5, lines 23-32 and column 6, lines 8-13.

The addition of '521 does not make up for the deficiencies of the other two documents. It is cited in the specification as showing one example of the general "type" of vessel used. However, as noted in the rejection, '521 does not teach delivering gel. The problem addressed by '521 concerns overrun which means that the amount of product dispensed varies as the container empties, and it often means that product remains in the container that cannot be dispensed. The user requirements thus broadly concern emptying the container and having a uniform product dispensed. Appellants' invention is concerned with packaging a gel so that the packaging can be used to dispense more than one dose without compromising the sterility of the remaining doses. These user requirements are very different. Moreover, one of ordinary skill in the art at the time the invention was made did not put wound gels in barrier aerosol containers and would not look to the hair coloring/shaving cream art of '521.

It is asserted in the rejection that this is simply an argument against the references individually. However, contrary to that position, Appellants submit that they

must provide comments on the cited art. Explaining the inapplicability of a piece of art does not, in and of itself, mean Appellants are arguing that piece by itself.

Further, according to the rejection, "US '223 is relied upon for teaching gel can be delivered from a pressurized aerosol container." Appellants have explained why the actual teaching of US '223 is inapplicable here. As noted above, the purpose of the package of '223 is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. To say that "[I]t necessary (*sic*) follows from the teaching of EP '081 and US '223 that one would use (*sic*) single compartment vessel when there was no issue of reactivity or degradation of components of the composition" guts the whole teaching of US '223. While it may be "proper to take into account not only the specific teachings of the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom", one cannot gut the actual teachings of the references to combine them for some superficial notion. It cannot be casually argued that the rational to combine teachings "may be expressly or impliedly contained in the prior art" when the rational is neither. This is the situation here.

Consequently, the combination of EP '081 and US '223 cannot teach what it is argued in the rejection to teach. Then, throwing in US '521, which actually shows one example of the general "type" of vessel used, does nothing to rehabilitate what is not taught by the combination of EP '081 and US '223. In view of all that, the combination of EP '081, US '223 and US '521 cannot teach the claimed invention to one of ordinary skill in the art.

Moreover, one of ordinary skill in the art of wound care would not be expected to be skilled in the non-analogous art of barrier aerosol vessels. As already discussed above, the invention in '521 is directed at dispensing foaming compositions such as those used in hair coloring or shaving cream. The user requirements in wound care are not comparable to the user requirements in hair coloring or shaving cream. For instance, again as noted above, the problem addressed by '521 concerns overrun which means that the amount of product dispensed varies as the container empties and often means that product remains in the container that cannot be dispensed. The purpose of the inventors of '521 was to provide better dispensing of hair colorants and shaving

cream. The user requirements in the hair coloring or shaving cream field noted in '521 broadly concern emptying the container and having a uniform product dispensed. Appellants' invention is concerned with packaging a gel so that the packaging can be used to dispense more than one dose without compromising the sterility of the remaining doses. Clearly, this purpose and these user requirements are very different and non-analogous.

Accordingly, one of ordinary skill in the art of wound care would not combine the documents as they were combined in the rejection.

(iii) Conclusion

In view of the arguments above, reconsideration of this application and reversal of the rejection are respectfully requested.

Respectfully submitted,

ConvaTec Inc.
Patent Department
100 Headquarters Park Drive
Skillman, NJ 08558

Date: August 19, 2009

John M. Kilcoyne
Attorney for Appellants
Reg. No. 33,100
Phone: 908-904-2372

(8) CLAIMS APPENDIIX

Claims

1. (Canceled)
2. (Canceled)
3. (Canceled)
4. (Canceled)
5. (Previously presented) A self-sealing barrier aerosol vessel, under positive pressure, which minimizes contamination, containing multiple doses of a wound gel for the treatment of wounds wherein the gel comprises:
   (a) from about 0.05% to 10% by weight of a natural gelling agent;
   (b) from about 1.0% to 10% by weight of a hydrocolloid;
   (c) from about 5.0% to 30.0% by weight of an alkylene glycol; and
   (d) at least 50% by weight of water.
6. (Previously presented) The self-sealing barrier vessel as claimed in claim 5 wherein the gel is sterile.
7. (Canceled)
8. (Previously presented) A method of making a self-sealing barrier aerosol vessel, under positive pressure, which minimizes contamination, comprising multiple doses of a wound gel, the method comprising the steps of:
   (i) filling an inner container with multiple doses of a wound gel, said inner container being contained within an outer casing container;
   (ii) sealing the inner container with an opening valve; and
   (iii) introducing a pressure medium between the inner container and the outer casing container.
9. (Previously presented) A method of making a self-sealing barrier aerosol vessel, under positive pressure, which minimizes contamination, comprising multiple doses of a wound gel, the method comprising the steps of:
   (i) filling an inner container with multiple doses of a non-sterile wound gel, said inner container being contained within an outer casing container;
   (ii) sealing the inner container with an opening valve;

(iii) sterilizing the vessel and gel contained within it; and

(iv) introducing a pressure medium between the inner container and the outer casing container.

10. (Previously presented) A multiple dose, sterile wound gel contained within a self-sealing barrier aerosol vessel, under positive pressure, which minimizes contamination.

Claims 11-13 (Canceled)

14. (Previously presented) A method for the treatment of a sinus wound comprising discharging into a sinus cavity a wound gel from a self-sealing barrier aerosol vessel, under positive pressure, which minimizes contamination, containing multiple doses of a wound gel.

15. (Previously presented) A method for treatment of a wound comprising discharging onto the wound a wound gel from a self-sealing barrier aerosol vessel, under positive pressure, which minimizes contamination, containing multiple doses of a wound gel wherein said wound gel is sterile.

16. (Canceled)

17. (Canceled)

18. (Previously presented) The method of claim 15 wherein said gel has a viscosity of between 150 and 800 Pas.

19. (Previously presented) A method for treatment of a wound comprising discharging onto the wound a wound gel from a self-sealing barrier aerosol vessel, under positive pressure, which minimizes contamination, containing multiple doses of a wound gel wherein said gel-containing vessel is prepared by the following steps:

(i) filling an inner container of said vessel with multiple doses of a non-sterile gel;

(ii) sealing the inner container with an opening valve;

(iii) sterilizing said vessel and gel; and

(iv) introducing a pressure medium between the inner container and the outer casing container.

20. (Previously presented) A method for dispensing multiple doses of a preservative-free therapeutic gel from a single dispenser to a wound in need of such gel comprising the steps of:

(a) providing a self-sealing barrier aerosol dispenser, under positive pressure, which minimizes contamination, with said gel therein by

(i) preparing said self-sealing barrier aerosol dispenser to comprise an inner container and an outer casing container;

(ii) filling said inner container with multiple doses of said gel;

(iii) sealing said inner container with an openable and closeable dispensing valve;

(iv) sterilizing the container and multiple doses of gel therein; and

(v) introducing a pressure medium between said inner container and said outer casing container; and

(b) opening and closing said dispensing valve to dispense two or more doses of said gel into said wound, whereby the risk of contamination of the gel remaining in said dispenser is substantially eliminated.

(9) EVIDENCE APPENDIX

None.

Docket No. CV 0244

(10) RELATED PROCEEDINGS APPENDIX

Appeal No. 2006-2797; decision attached on the following pages.

AUG 19 2009

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MICHAEL J. WARING, and ELIZABETH JACQUES

Appeal No. 2006-2797
Application No. 09/341,821

ON BRIEF

Before ADAMS, MILLS, and LEBOVITZ, Administrative Patent Judges.

LEBOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to an aerosol barrier vessel comprising a wound gel. The examiner has rejected the claims as obvious over prior art. We have jurisdiction under 35 U.S.C. § 134. We affirm-in-part.

Background

The application relates to multi-dose wound gels. Specification, page 1, lines 7-10. "The gels are usually packaged in a tube and applied to the wound from the tube." Id., page 1, lines 28-29. "If packaged in a multi-dose tube there is a risk with some gels that once the tube is opened, bacteria will enter the tube and proliferate in

the gel." Id., page 1, lines 30-33. This has caused manufacturers to add preservatives to gels. Id., page 1, lines 33-35. "Some health care professionals are reluctant to introduce preservatives to a wound and so use single dose tubes containing sterile gel." Id., page 1, lines 35-37. The application describes a solution to this problem by packaging wound gels in barrier aerosol vessels which minimize contamination once opened, and thus do not require the addition of preservatives. Specification, page 2, lines 9-14.

Claim construction

Claims 1-6, 8-10, 13-15, and 17-20, which are all the pending claims in this application, are on appeal. There are three prior art rejections, each involving a different set of claims (1-4, 13, and 17; 5, 6, 10, 14, 15, and 18; and 8, 9, 19, 20). Brief, page 2. The claims stand or fall together in each of the three sets because Appellants have grouped the claims together under a single heading without providing separate reasons for patentability for any individual claims. 37 CFR ¶ 41.37(c)(vii). We select a single claim from each set to decide the appeal as to the ground of rejection.

Claims 1-4, 13, and 17

1. A self-sealing barrier aerosol vessel containing multiple doses of a wound gel for the treatment of wounds.

Claims 5, 6, 10, 14, 15, and 18

5. A vessel as claimed in claim 1 wherein the gel comprises:
(a) from about 0.05% to 10% by weight of a natural gelling agent;
(b) from about 1.0% to 10% by weight of a hydrocolloid;
(c) from about 5.0% to 30.0% by weight of an alkylene glycol; and
(d) at least 50% by weight of water.

Claims 8, 9, 19, 20

For reasons discussed below, although claims 8 and 9 were not separately argued, we have addressed them separately.

8. A method of making a self-sealing barrier aerosol vessel comprising multiple doses of a wound gel, the method comprising the steps of:
(i) filling an inner container with gel, said inner container being contained within an outer casing container;
(ii) sealing the inner container with an opening valve; and
(iii) introducing a pressure medium between the inner container and the outer casing container.

9. A method of making a self-sealing barrier aerosol vessel comprising multiple doses of a wound gel, the method comprising the steps of:
(i) filling an inner container with non-sterile gel, said inner container being contained within an outer casing container;
(ii) sealing the inner container with an opening valve;
(iii) sterilizing the vessel and gel contained within it; and
(iv) introducing a pressure medium between the inner container and the outer casing container.

Claim 1 is drawn to a self-sealing barrier aerosol vessel. The specification explains that a barrier aerosol vessel is "of the type where the product to be dispensed and the pressure generating media, ie [sic] the propellant, are maintained in isolation through separation on opposite sides of a barrier." Specification, Page 2, lines 14-17. The specification describes "[t]hree main variants of barrier vessels" which are known in the prior art. Id., page 2, line 33-page 3, line 33. Each contains two separate compartments, one holding the product, and the other, the gas propellant which is used

to expel the product from the vessel. The gas-filled compartment is separated by a "barrier" from the product-filled compartment. When the vessel is opened, the pressure in the product-filled compartment is reduced, causing the gas-filled compartment to push against the product-filled compartment and expel the product from it. Id., page 3.

The barrier aerosol is "self-sealing." This phrase was added by an amendment filed September 3, 2003. The specification does not provide a definition of what it means to be "self-sealing" nor a description of the structure necessary to meet this limitation. However, claims "'must be read in view of the specification, of which they are a part.' .... [T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" Phillips v. AWH Corp., 415 F.3d 1303, 1315, 75 USPQ2d 1321, 1327 (Fed. Cir. 2005) (internal citations omitted).

According to the specification, "because there is positive pressure in the container, the vessel can be made to be self-sealing." Specification, page 2, lines 18-20. "This aids maintenance of product [wound gel] sterility." Id., page 2, lines 20-21. It is also stated that, when the product container is sealed with the "opening valve" after filling and steam sterilization, "pressure medium can then be introduced [into the second compartment] without compromising the sterility of the product." Id., page 4, lines 6-11; page 4, line 34-page 5, line 5. Experiments that mimicked clinical use (i.e., discharge of gel from the opening valve) were performed to show that that "micro-organisms do not proliferate in the gel contained in the barrier vessel." Id., page 8, line 28-page 9, line 17. In view of the specification's reference to the opening valve with respect to maintaining wound gel sterility, we interpret the claimed requirement that the vessel is "self-sealing"

to be a property of the opening valve. We further construe "self-sealing" to have its "ordinary and customary meaning" (Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996)), i.e., to seal by itself ("self") without assistance.

Making the vessel "self-sealing" protects the product contained in the aerosol vessel from contamination by sealing it up after the product has been discharged. This is consistent with the vessel's purpose "to package a [wound] gel in multi-dose packaging which minimises contamination once opened." Id., page 2, lines 9-11. Neither the claims nor the specification require the self-sealing opening valve to have a particular structure.

In sum, we construe "self-sealing barrier aerosol vessel" to be a vessel having a first compartment for containing the wound gel and second compartment, which is isolated from it, that contains pressurized gas to facilitate discharge of the wound gel from the vessel. The first compartment comprises a valve or port, through which gel can be introduced into the vessel or discharged from it, and which seals up by itself after a single dosage of gel is expelled from the vessel.

Anticipation

Claims 1-4, 13 and 17 stand rejected under 35 U.S.C. § 102(b) as anticipated by Jass.[1]

[1] Jass et al. (Jass), U.S. Pat. No. 3,976,223, issued Aug. 24, 1976

Jass discloses a "valve-actuated aerosol for separately storing and simultaneously dispensing" flowable material. Jass, Abstract. As shown in Fig. 1, the package comprises two separate chambers (inner container [4] and outer container [2]) which are filled with "flowable" materials. The materials are dispensed through a "dispensing valve" [14] using a "valve actuator" [16]. The package also contains a pressure sealed lower chamber [B]. When the dispensing valve [14] is opened ..., the pressurized gas is the lower pressure sealed chamber [B] causes the piston to move away from the container bottom and toward the dispensing valve end of the container." Id., column 2, lines 57-62. The piston movement pushes the materials in the inner and outer containers through the dispensing valve. Jass descries the use of the aerosol package to dispense a "strippable gel bandage" for burn treatment. Id., column 9, line 16-column 10, line 29.

The Examiner takes the position that Jass describes an aerosol package that meets all the limitations of claim 1. For the claimed requirement that the vessel contain "multiple doses of a wound gel," the Examiner relies on Jass's disclosure (column 4, lines 52-56) that the metered amounts of material are dispensed from the package, implying that it contained multiple doses. Answer, page 5, lines 16-18. The Examiner states that "[t]he cut off of the flow as well as the self-sealing properties of the aerosol inherently prevent contamination of the content of the aerosol." Id., page 5, lines 18-20.

Appellants argue that "the container in Jass et al. is not self-sealing as required in the rejected claims." Brief, page 3. They contend that the "self-sealing plug in the container bottom" described by Jass is used to keep the lower chamber of pressured with gas, not to self-seal the container to avoid contamination. Id.

To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383, 58 USPQ2d 1286, 1291 (Fed. Cir. 2001). We concur with the Examiner that Jass's "valve-actuated aerosol package" contains all the elements of the claimed "self-sealing barrier aerosol vessel," anticipating claim 1.

Jass's dispensing valve is kept shut with a compression spring [30] that prevents the flowable materials present in the containers from entering into the exit passageway. Jass, column 3, lines 28-47. The exit ports are opened by depressing the compression spring to actuate the dispensing valve. Id., column 4, lines 35-40. Once actuated, the "the gas under pressure in pressure tight chamber B" forces the piston upward, pushing the flowable materials through the exit passageway and out through the dispensing valve. Id., column 4, lines 38-45. As a result, "a uniform, metered amount of the flowable material" is discharged from the package. Id., column 4, lines 46-58. Jass indicates that "dispensing valve assembly" forms "a pressure tight closure when the valve is closed. Id., column 3, lines 20-24. This structure described by Jass can be characterized as "self-sealing" since the compression spring [30] in combination with the lower pressurized container keep the valve shut. Jass states that the "relative metering" of the flowable material from the container "is constant throughout the life of the dispenser," indicating that it contains "multiple doses," as required by claim 1. Id., column 4, line 66-column 5, line 2.

Appellants state that the "self-sealing plug" at column 2, lines 53-57 of Jass, relates to the "pressure sealed chamber," and is not "self-sealing" as required by the claims. Brief, page 3. We agree that the self-sealing plug described by Jass is for the

purpose of sealing the lower chamber. However, this disclosure is different from the description of the dispensing valve (as discussed above) which we have concluded satisfies the claimed requirement that the vessel is "self-sealing."

Appellants contend that the Jass's package does not "address the avoidance of contamination during its use," the advantage they describe in the specification for the claimed subject matter. Brief, page 3. As pointed out by the Examiner, this limitation is not recited in the claims. Answer, page 5, ¶ 2. More to the point is whether Jass describes an aerosol package that meets all the expressly recited limitations of claim 1. For the reasons discussed above, we find that it does. Accordingly, we conclude that there is adequate evidence to establish a case of prima facie anticipation of claim 1. Appellants have not provided convincing arguments to rebut it. Claims 2-4, 13, and 17 fall together with claim 1.

Obviousness

Jass in view of Court

Claims 5, 6, 10, 14, 15, and 18 stand rejected under 35 U.S.C. § 103(a) as obvious over Jass in view of Court.[2]

Claim 5 requires that the gel comprises four components (a)-(d). The Examiner cites Court for teaching a wound dressing that contains these four components, arguing that it would have been obvious to have replaced the wound dressing in Jass with the gel disclosed in Court for the reason that Jass teaches its package as useful for

[2] Court et al. (Court), EP 0 666 081 A1, published Aug. 9, 1995

delivering "flowable materials," including wound gels that have the characteristics of the composition described by Court. Answer, page 7.

The examiner bears the initial burden of showing unpatentability. See e.g., In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness requires evidence that the prior art suggested to those of ordinary skill in the art that they should make the claimed subject matter, and that those skilled in the art would have been motivated to do so with a reasonable expectation of success. See In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970); In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Jass teaches its package for "separately storing and simultaneously dispensing ... a plurality of flowable materials." Jass, Abstract. Jass describes his aerosol container as a solution to prior art attempts to package materials in a multi-compartment aerosol container which must be kept separate from each other until used. Id., column 1, lines 13-65. "The typical examples of materials which react when mixed and, because of such reaction, must be kept separated from each other until used are ... dyes and developers for hair colorings, epoxy resin based paints and cements which harden upon mixing." Id., column 1, lines 30-36. Jass's strippable gel bandage is comprised of two phases that are separately stored in the two-compartment aerosol package. When expelled on to the skin, they gel "at the site of use." Id., column 9, lines 42-43.

Court teaches a composition in which all the ingredients are present together, and does not disclose or suggest that they require separate compartmentalization. We see no reason which would have motivated the skilled artisan to have used Jass's two-

compartment container for storing Court's single composition. This rejection is reversed.

Sperry in view of Jass

Claims 8, 9, 19, and 20 stand rejected under 35 U.S.C. § 103(a) over Sperry[3] in view of Jass.

Although Appellants did not separately argue any of the claims in this group, because we found claim 8 to be anticipated, rather than obvious over the prior art, we decided to separately address claims 9, 19, and 20.

Claim 8

Claim 8 has three steps: 1) filing the inner container of the aerosol vessel with gel; 2) sealing it with an opening valve; and 3) introducing pressure into the vessel "between the inner container and the outer casing container." The Examiner states that these three steps are taught by Sperry. Answer, page 9. She concludes that it would have been obvious to have used Sperry's container for a wound treating composition as described in Jass, but does not clearly articulate the motivation for making this combination. Id.

Appellants argue that Sperry does not "teach or suggest a dispensing vehicle that contains multiple doses of wound-treating material." Brief, page 4. They also argue that Sperry teaches dispensing a liquid, and not a wound gel. Id., page 5.

We do not find Appellants arguments persuasive. Sperry teaches that an aerosol container for dispensing wound cleaning compositions can be sterilized after filling, either by irradiation or autoclaving. Sperry, column 2, lines 64-68; column 6, lines 20-

[3] Sperry et al. (Sperry), U.S. Pat. No. 5,059,187, issued Oct. 22, 1991

23. When autoclaving is used to sterilize the container, the container is filled with wound cleansing solution, sealed, autoclaved, and then filled with a gas propellant. Id., column 5, lines 8-21. In our view, these steps are the logical and necessary steps that would be required to prepare Jass's aerosol container for use. Jass's container holds gel in an inner container and therefore must be filled with it, meeting step (i) of claim 8; it also has an "opening valve" that seals the inner container (column 3, lines 20-28, stating that the "dispensing valve assembly" forms "a pressure tight closure when the valve is closed") as required in step (ii); a pressure medium is introduced "between the inner container and the outer casing container," meeting step (iii) (Fig. 2, compare [B] and [54]; the gas is introduced into B as described on column 4, lines 24-28).

We recognize that Jass does not expressly state that the three steps required by claim 8 are carried out, but such steps would be necessary to prepare his disclosed aerosol package filled with the components of the gel bandage. To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." Atlas Powder Co. v. Ireco, Inc., 190 F.3d 1342, 1346, 51 USPQ2d 1943, 1945 (Fed. Cir. 1999). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." Id., 190 F.3d at 1347; 51 USPQ2d at 1946. For the foregoing reason, we conclude that these conditions are met here.

We designate this as a new grounds of rejection because we are not relying on the combination of references upon which the Examiner based the § 103 rejection. Rather, we are setting forth a new ground of rejection of claim 8 as anticipated under § 102(b) by Jass.

Claims 9, 19, and 20

For claims 9, 19, and 20, which require a sterilizing step, we concur with the Examiner that such claims are obvious over Jass and Sperry, but for different reasons than stated by the Examiner.

In making an obviousness determination, it is necessary to consider the differences between the claimed invention and the prior art in the context of the level of the person of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. 1, 13-14, 148 USPQ 459, 465 (1966). In this case, the difference between the claimed subject matter and Jass is that the Jass does not teach or expressly suggest a step in which the vessel and gel are sterilized as required by the claims.

As observed by the Examiner, this deficiency is met by Sperry. Sperry teaches that wounds are normally cleaned and irrigated with sterile solutions. Sperry, column 1, lines 10-25 and 60-63. The compositions can be sterilized prior to introduction into the container, or when already loaded into the container as described by Sperry (column 2, lines 60-68; column 5, lines 7-21).

In order to combine references, there must be some teaching, suggestion, or motivation found in the prior art or from the general knowledge available to the skilled worker. "[T]he teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." In re Kahn, 441 F.3d 977, 987-88, 78 USPQ2d 1329, 1336

(Fed. Cir. 2006). Here, we find that the nature of the problem – to treat a burn wound – would have suggested to the skilled worker (e.g., a healthcare provider) that Jass's wound gel bandage requires sterilization, and would have been motivated to accomplish it according to Sperry, as a choice of a conventional technology for accomplishing sterilization. Accordingly, it is our conclusion that claims 9, 19, and 20 are obvious over the combination of Sperry and Jass. Because our reasoning in affirming this rejection differs from the Examiner, we designate it as a new ground of rejection to provide Appellants with a fair opportunity to respond to it.

In response to arguments made by Appellants distinguishing Sperry on the basis that it does not teach "dispensing multiple doses," we concur with the Examiner that Sperry is "relied upon for the solely teaching of the method of making the aerosol." Answer, Page 10.

Other issues

Appellants have admitted in their application that barrier aerosol vessels were known in the prior art. Specification, pages 2-4. Upon return of this application to the technology center, we suggest that the Examiner reconsider the prior art as it pertains to claims 5, 6, 10, 14, 15, and 18 and make specific findings on whether any of the prior art barrier aerosol vessels are "self-sealing" and for use with a single composition in contrast to Jass's teaching. Among the prior art, we call the Examiner's attention to pages 1680-81 of Remington,[4] particularly Fig. 7 which shows a barrier aerosol vessel with a metering valve.

[4] Remington: The Science and Practice of Pharmacy, Vol. II, pp. 1680-81 (1995)

Summary

We affirm the rejection of claims 1-4, 13, and 17 as anticipated by prior art and the rejection of claim 9, 19, and 20 as obvious over prior art. We set forth a new grounds of rejection for claim 8 as anticipated by prior art. The rejection of claims 5, 6, 10, 14, 15, and 18 is reversed.

Time Period for Response

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

AFFIRMED-IN-PART/37 C.F.R. § 41.50(b)

Donald E. Adams)
Administrative Patent Judge)
)
)
Demetra J. Mills) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
Richard M. Lebovitz)
Administrative Patent Judge)

RML/jlb

T R Furman
Bristol Myers Squibb Company
100 Headquarters Park Drive
Skillman, NJ 08558

Notice of References Cited	Application/Control No. 09/341,821	Applicant(s)/Patent Under Reexamination Appeal No. 2006-2797	
	Examiner	Art Unit	Page of

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
X	U	"Remington. The Science and Practice of Pharmacy," in Vol. II, The Science and Pharmacy, 1680-1681 (Easton, Pennsylvania , Mack Publishing Company 1995)
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

The Science and Pharmacy

1995

MACK PUBLISHING COMPANY
Easton, Pennsylvania 18042

Remington: The Science and Practice of Pharmacy

Volume II

Table 4—Properties of Compressed Gases

Property	Carbon dioxide	Nitrous oxide	Nitrogen
Molecular formula	CO_2	N_2O	N_2
Molecular weight	44	44	28
Boiling point °F	−109[a]	127	−320
Vapor pressure, psia, 70°F	852	735	492[b]
Solubility in water,[c] 77°F	0.7	0.5	0.014
Density (gas) g/mL	1.53	1.33	0.96699

[a]Sublimes
[b]At the critical point (−233°F)
[c]Volume of gas at atmospheric pressure soluble in one volume of water.

Barrier Type Systems

These systems separate the propellant from the product itself. The pressure on the outside of the *barrier* serves to push the contents from the container. The following types are available.

Piston Type—Since it is difficult to empty the contents of a semisolid from an aerosol container completely, a piston-type aerosol system has been developed. This utilizes a polyethylene piston fitted into an aluminum container. The concentrate is placed into the upper portion of the container. The pressure from nitrogen (about 90 to 100 psig), or a liquefied hydrocarbon gas, pushes against the other side of the piston and, when the valve is opened, the product is dispensed. The piston scrapes against the sides of the container and dispenses most of the product concentrate.

The piston-type aerosol system is shown in Fig 4. This system has been used successfully to package cheese spreads, cake decorating icings and ointments. Since the products which use this system are semisolid and viscous, they are dispensed as a lazy stream rather than as a foam or spray. This system is limited to viscous materials since limpid liquids, such as water or alcohol, will pass between the wall of the container and the piston.

Plastic-Bag Type—This system consists of a collapsible plastic bag fitted into a standard, three-piece, tinplate container as shown in Fig 5. The product is placed within the bag and the propellant is added through the bottom of the container. Since the product is placed into a plastic bag, there is no contact between the product and the container wall except for any product which may escape by permeation through the plastic bag.

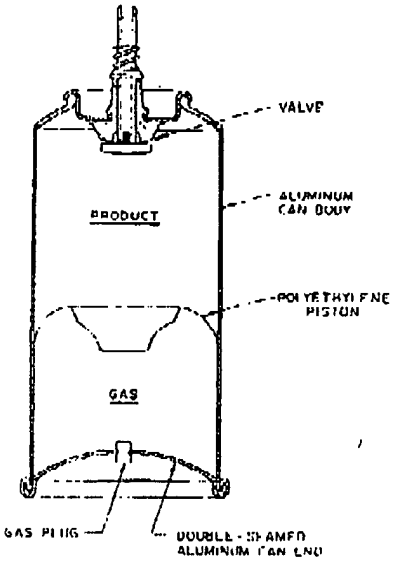

Fig 4. Free-piston aerosol system.

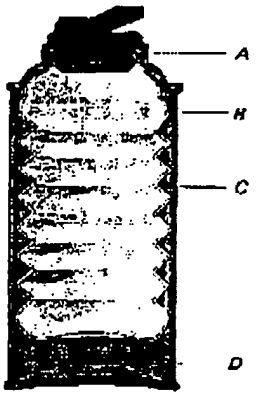

Fig 5. Plastic-bag aerosol system: *A*: valve; *B*: standard three-piece tin-plate container, *C*: plastic bag; *D*: gas filling port.

Limpid liquids, such as water, can be dispensed either as a stream or fine mist depending on the type of valve used, while semisolid substances are dispensed as a stream. In order to prevent the gas from pinching the bag and preventing the dispensing of product, the inner plastic bag is accordion-pleated. This system can be used for a variety of different pharmaceutical and nonpharmaceutical systems, including topical pharmaceutical products as a cream, ointment or gel.

A modification of this system dispenses the product as a gel which will then foam. By dissolving a low-boiling liquid such as isopentane or pentane in the product, a foam will result when the product is placed on the hands and the warmth of the hands will cause vaporization of the solvent. This system, as well as the piston system, is used in post-foaming shave gels.

Can-In-Can Systems—Figure 6 illustrates a system consisting of an aluminum can into which an aluminum thin-walled can has been inserted. This inner can is glued to the outer can and forms a gas-tight seal. Then, the neck of the can is fabricated. The propellant (any acceptable type) is added through a small opening in the bottom of the can which

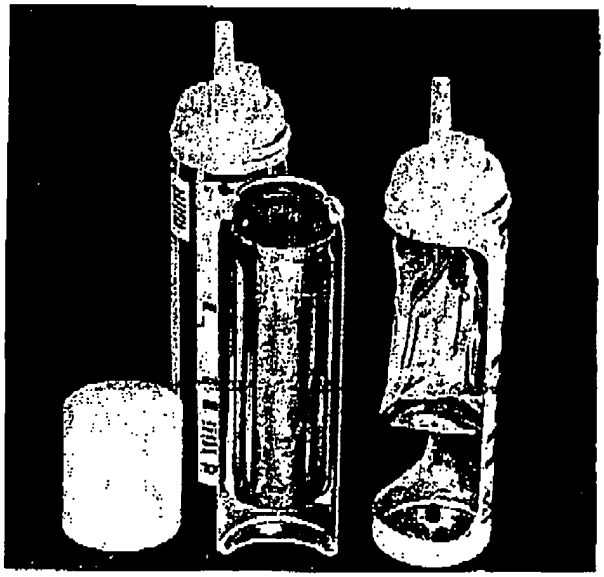

Fig 6. Cross section of the Lechner barrier pack. It consists of a rigid or flexible inner bag which can be evacuated over 95% depending upon the viscosity of the product (courtesy, Lechner GMBH).

is sealed with a rubber plug. A recent addition to this system includes replacement of the inner aluminum pouch with an inner plastic bag made of organic polymers. Sufficient space remains between this bag and the walls and the bottom of the outer container to accommodate sufficient propellant to completely evacuate the product.

Another such system is essentially the same except that the inner aluminum can is supplied separately from the outer can. This allows for insertion of liquified gas prior to adding the inner can (filled with product) and crimping the valve in place. Figure 7 shows this system. Systems illustrated by Figs. 6 and 7 have been suggested for use with a variable-dose valve for dispensing nasal aerosols containing aqueous solutions of insulin.

Other variations of these systems include using a sealed laminate pouch, which is placed into an outer aluminum can. The product is injected into the pouch, and compressed air is added either through a special opening in the valve or by using the under-the-cup method of gassing. Another system includes filling the product into a latex bag which then expands. The energy caused by the *stressed bag* will release the product when the valve is opened.

Propellants

The propellant generally is regarded as the "heart" of the aerosol package. In addition to supplying the necessary force to expel the product, the propellant must also act as a solvent and diluent and has much to do with determining the characteristics of the product as it leaves the container. Various chemical compounds have been used as aerosol propellants.

Compounds useful as propellants can be classified as

Liquefied gases
- Fluorinated chlorinated hydrocarbons (halocarbons)
- Hydrochlorofluorocarbons
- Hydrochlorocarbons
- Hydrocarbons
- Hydrocarbon Ethers

Compressed gases

Liquefied Gases

The liquefied gas compounds have widespread use as propellants since they are extremely effective in dispersing the active ingredients into a fine mist or foam, depending on the form desired. In addition, they are relatively inert and nontoxic. They have the added advantage that the pressure within the container remains constant. Two types of liquefied gases are used. The fluorinated hydrocarbons find greater use since they are nonflammable as contrasted to the flammable hydrocarbons. The hydrocarbons are advantageous since they are less expensive than fluorocarbons and, generally, are environmentally acceptable.

Chlorofluorocarbons (CFCs) can be used for the following exempted products:

- Metered-dose steroid drugs for nasal inhalation.
- Metered-dose steroid drugs for oral inhalation.
- Metered-dose adrenergic bronchodilator drugs for oral inhalation
- Contraceptive vaginal foams
- Metered-dose ergotamine tartrate drug products administered by oral inhalation.
- Certain topical pharmaceutical aerosols containing antibiotics

These pharmaceutical aerosols include metered dose inhalers (MDIs) which can be formulated using the chlorofluorocarbons 11, 12, and 114.

Liquefied gases provide a nearly constant pressure during packaging operations and have a large expansion ratio. Several of the fluorinated hydrocarbons have an expansion ratio of about 240, that is, 1 mL of liquefied gas will occupy a volume of approximately 240 mL if allowed to vaporize.

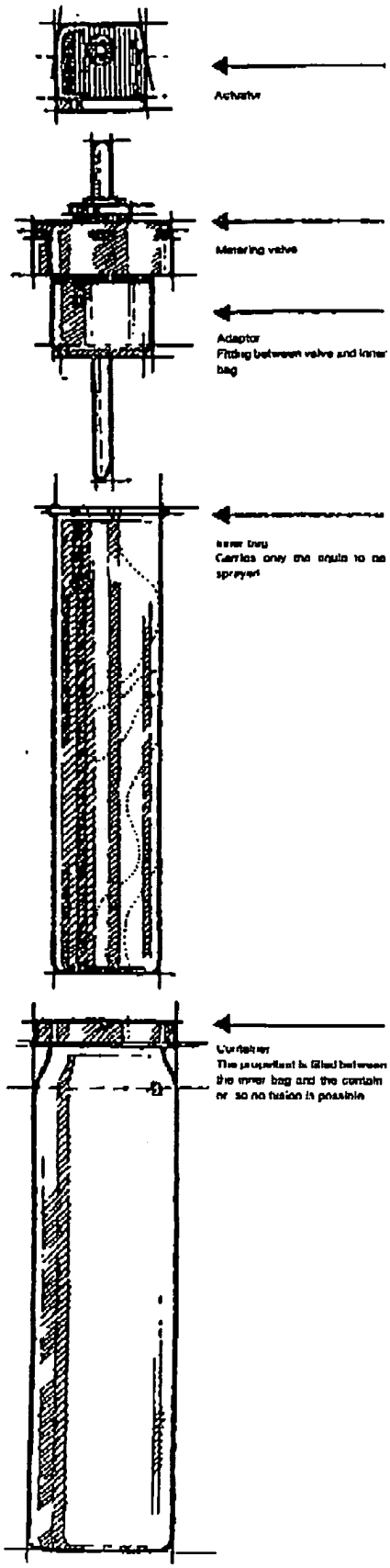

Fig 7. Metered-dose barrier package designed for delivering small quantities of liquids or viscous liquids, creams and ointments.